Ethical Considerations:

Managing Your IRB

The four key personnel responsible for managing your IRB :

1. Chair
2. Members
3. Administrator
4. Support staff

IRB Chair

There are no federal requirements for the IRB Chair. However, the regulations require that "In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas." (38CFR16.107(a)) Thus, previous IRB experience and ability to work well with group process are imperative to being a successful IRB Chair.

IRB Members

"Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." (38CFR16.107(a))

To provide appropriate review, the IRB needs to be able to devote the time necessary to thoroughly discuss a protocol. Generally, IRB members are not paid and must juggle IRB membership with numerous other responsibilities. To find and retain qualified individuals, IRB membership needs to be rewarded and valued in the institution.

IRB Administrator

In today's oversight environment it is imperative to have a trained, professional IRB administrator. The role of IRB administrator may vary among institutions, but key roles may include:

- Serves as liaison between IRB and investigators, assisting investigators with protocol review
- Stays up to date with new policies and disseminates information
- Helps the IRB Chair train new IRB members
- Maintains library and resource materials pertaining to human subject protection
- Monitors IRB performance

IRB Support Staff

Many important oversight and management issues remain unresolved. For example, there is no definition of the optimal number of research studies for an IRB to review each year or an agreed upon number of support staff necessary to run an IRB. ***Insufficient resources may compromise performance such that minutes may lag, comments back to researchers may be delayed, and proper documentation may not occur.***

IRB performance measures can help evaluate whether the resources devoted to support staff are adequate. Measures may include:

- Number of research studies submitted, stratified by disease focus
- Number of research studies exempted from review
- Number of research studies given expedited review
- Average time from submission of a research protocol to initial review

IRB performance can be evaluated along three domains:

1. Technical—Do the means employed produce the ends desired? (e.g., research participants are adequately protected)
2. Economic—Are the means employed the most efficient for producing the ends desired?" (e.g., timeliness of review process)
3. Legal/Social/Political—Are the means acceptable to the judicial (regulatory), social and political structures in which you operate?" (e.g., NCQA accreditation)

For information about certification for IRB Professionals visit: http://www.primr.org/arena.html.

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